K131630

510(k) Summary

Puritan Amies Medium

5.1 Sponsor

Puritan Medical Products LLC

31 School St., Guilford, ME

04443

OCT 2 1 2013

Contact: Mehdi Karamchi

Telephone Number: 207-876-3311

Date: May 29, 2013

5.2 Device Name

Classification Name: Microbiological Specimen Collection and Transport Device

Common Name: Specimen Collection and Transport System

Proprietary Name: Puritan Amies Medium Collection and Transport System

5.3 Regulatory Information

A. Regulatory Section: 21 CFR 866.2900

B. Classification: Class I

C. Product Code: LIO, JTW, JTX

D. Panel: Microbiology

5.4 Predicate Device

BD CultureSwab™ Collection and Transport System manufactured by Copan Diagnostics Inc. of Italy

510K Number: K972448

5.5 Device Description

Puritan Amies Medium Collection and Transport System is comprised of a sterile peel pouch containing a rayon tipped swab applicator for collecting specimen and a polypropylene tube containing 4 ml of Amies medium with or without charcoal. The rayon tipped swab applicators are provided in different tip sizes to accommodate various specimen types.

Amies medium is a nonnutritive balanced salt solution containing inorganic phosphates to provide buffering capability, sodium chloride, potassium chloride, calcium chloride and magnesium chloride to provide essential ions that help maintain osmotic balance. Agar is a solidifying agent and gives a semi-solid texture to the medium. Sodium thioglycollate provides a reduced environment. It is recommended for maintaining the viability of aerobic, anaerobic and fastidious bacteria during the transport to the laboratory.

5.6 Intended Use

Puritan Amies Medium Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

5.7 Indication(s) For Use

Puritan Amies Medium Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

5.8. Substantial Equivalence statement

Puritan Amies Medium is similar in design, manufacturing and intended usage to the predicate device. Both Puritan and predicate device are single-use devices intended for collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria.

Puritan Versus Competitor Similarities		
Item	**Test Device**	**Predicate**
Intended USE	Puritan Amies Medium Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.	The Copan Venturi Transystem Amies Medium Without Charcoal products are sterile, single-use specimen collection chambers intended to preserve the viability of microorganisms after their collection and during their transport from the collecting area to the laboratory. These devices are intended for the collection, transport, and preservation of clinical specimens for bacteriological examination. Copan Venturi Transystem Amies Medium Without Charcoal is designed to support the viability of a wide variety of clinically important aerobic and anaerobic bacteria.
Single-use Device	Yes	Same
Medium Formulation	Sodium chloride Disodium phosphate Sodium thioglycollate Monopotassium phosphate Potassium chloride	Same

	Calcium chloride Magnesium Chloride Bacteriological Agar Charcoal (with Amies Charcoal)	
pH	7.3 ± 0.2	Same
Storage Temperature	4-25°C (refrigerated and room temperature)	Same
Container	Plastic round bottom tube	Same
Product Configuration	Medium in tubes & Plug System including Medium and swab in peel pouch option.	Same
Swab Shaft	Plastic	Same
Swab Tip	Rayon tipped swab	Same
Shelf Life	24 months	Same

5.9 Recovery Testing

To determine the ability of the Puritan Amies Medium to maintain viability of different strains of aerobes, anaerobes and fastidious bacteria, known inoculum of ATCC type culture and clinically significant microorganisms were inoculated into the Puritan Amies Medium and compared to the predicate device following Clinical and Laboratory Standards Institute (CLSI), M40-A guidelines. No significant differences in recovery were detected between samples obtained from Puritan Amies Medium vs. predicate device.

5.10 Stability Testing

Stability tests were performed on Puritan Amies Medium products to verify the ability of the aged products to maintain microbial recovery up to the expiry date.

5.11 pH Stability

The pH of the test device was measured at predetermined time intervals up to 24 month after manufacturing date. The test was performed using calibrated pH meter with random samples from three different lots of Puritan Amies Medium. All samples tested were found to maintain pH within the specified range.

5.12 Cytotoxicity

Cytotoxicity test was conducted to evaluate Glue, shaft and the rayon tipped swabs for potential cytotoxicity effect following ISO Elution Method-1X MEM Extract. No evidence of cytotoxicity was detected.

5.13 Sterilization

Puritan Amies Medium are sterilized by gamma irradiation and validated following ANSI/AAMI/ISO 11137:2006, Sterilization of health care products Radiation guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

PURITAN MEDICAL PRODUCTS, LLC
MEHDI KARAMCHI
V.P. OF SCIENTIFIC AFFAIRS
31 SCHOOL STREET
P.O. BOX 149
GUILFORD ME 04443-0149

October 21, 2013

Re: K131630
Trade/Device Name: Puritan Amies Medium Collection and Transport System
Regulation Number: 21 CFR 866.2900
Regulation Name: Microbiological specimen collection and transport device
Regulatory Class: I
Product Code: LIO, JTW, JTX
Dated: September 9, 2013
Received: September 11, 2013

Dear Mr. Karamchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): k131630

Device Name: Puritan Amies Medium Collection and Transport System

Indications for Use:

Puritan® Amies Medium Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Center for Devices and Radiological Health

Ribhi Shawar -S
2013.10.21 16:56:10 -04'00'